

Marx et al.  
U.S.S.N.: 10/533,826

**In the Drawings:**

Please substitute FIGS. 1-8, each entitled "REPLACEMENT SHEET," contained in the attached .ppt file for original FIGS. 1-8 of record.

### **Remarks**

Claims 1-47 were present in the application as filed, with claims 44-47 cancelled by preliminary amendment. In response to a restriction dated February 15, 2007, Applicants elected the claims of Group I (claims 1-10, and 34-36) and SEQ ID NO. 1 as a representative species of haptotactic peptide. The election was made without traverse and with the understanding that the withdrawn process claims would be rejoined if the elected claims were found allowable, and the withdrawn claims were amended to include all the limitations of the product claims.

In response to a first Office Action dated September 21, 2007, claims 2-6, 15-19, 26-30 and 42 were cancelled and new claims 48-51 were added.

A Request for Continued Examination was filed on January 8, 2009 to remove the finality of the Office Action of July 9, 2008. In a telephone interview with Examiner Audet, it was indicated that claims 1, 7-14, 20-25, 31-41, 43 and 48-51, as amended would be allowable pending submission of a terminal disclaimer over US 7,122,620 and new drawings and that claims 11-14, 20-25, 31-33, 37-41, 43 and 50-51 would be rejoined.

In a telephone conversation, the Examiner indicated that, due to the irreproducible quality of the originally filed drawings, replacement drawings would be required prior to allowance. Submitted herewith is a ppt file containing digital images to be used as black and white drawings. Accordingly, Applicant is not petitioning for color drawings. No new matter is introduced by the amendment.

### ***Double Patenting***

The claims are rejected on the ground of non-statutory obviousness double patenting as being unpatentable over claims 1-4 of U.S Patent No. 7,122,620 because, according to the Office Action, although the conflicting claims are not identical, they are not patentably distinct.

According to the Office Action:

“...the ‘620 patent is drawn to a peptide or any type of composition comprising identical SEQ ID NO. 1. Although the present application is to a “liposomal” composition comprising SEQ ID NO. 1, compositions comprising liposomes need no reference for an introduction. The use of liposomes to carry e.g. other active agents, in combinations with peptides has been well known in the art for over a decade a routinely used form of compositions. Absent evidence to the contrary the these [sic] specific liposomes carry some other unexpected property not routinely used within the peptide composition arts.”

Claims 1-4 of U.S. Patent No. 7,122,620 (hereinafter "the ‘620 Patent") are directed to a haptotactic peptide or composition comprising a haptotactic peptide identical to that of SEQ ID NO:1 of the instant Application. The ‘620 patent, however, does not teach or suggest the combination of a haptotactic peptide of SEQ ID NO. 1 with a liposome as a delivery vehicle for other unrelated biologically active compounds, e.g. a drug or a fluorescent dye.

Although the use of liposomes to carry other active ingredients is well known in the art, **the haptotactic peptide-liposomal compositions of the present invention do have other unexpected properties.** What was not known prior to the discovery by the inventors was the unexpected property of the haptotactic peptide-liposomal composition **to significantly enhance the composition’s uptake by different cell types.** This novel and unexpected property could not have been predicted at all and renders the compositions of the invention useful for a variety of uses, first and foremost as drug delivery vehicles for delivering other molecules unrelated to the haptotactic peptides themselves. Thus, the use of the compositions of the invention in turn may enhance the uptake of a biologically active agent present within the liposomes. This novel and inventive utility is exemplified in the present application in including, for example, the anti-cancer drug doxorubicin or the fluorescent dye rhodamine. As described in the instant specification (Example 4, paragraphs [0152]-[0154]), the uptake of either the free haptotactic peptide or the free liposomes into cells was significantly lower than the

uptake of the haptide-liposomal composition of the invention comprising the drug or the fluorescent dye. This was empirically determined and could not have been predicted.

The inquiry for non-statutory obviousness-type double patenting is similar to that for obviousness under 35 U.S.C. 103. Under *KSR*, the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398. Such is not the case here. Rather, as discussed above, the instantly claimed combination is more than the predictable use of prior art elements according to their established functions. Thus, Applicants respectfully submit that in view of the teachings of the '620 patent, the claimed peptide/liposome combination is not an obvious variation of the earlier claimed composition and it would not have been obvious to the skilled artisan to make the claimed combination since this new composition is unique in its structure and function, and possesses unexpected properties. Accordingly, the haptotactic peptide-liposomal compositions of the present invention would not have been obvious in view of the '620 Patent.

Reconsideration and withdrawal of the double patenting rejection is requested.

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In view of the forgoing amendments and arguments, the claims are believed in condition for allowance and such action is respectfully requested. Additionally rejoinder of the method claims is requested. The Examiner is invited to contact Applicants' undersigned representative with any questions that arise in connection with the present application.

Respectfully submitted,

Dated: January 27, 2009

A handwritten signature in cursive script that reads "Kathy Smith Dias". The signature is written in black ink and is positioned above the printed name and contact information.

Kathy Smith Dias, Reg. No.: 41,707  
Attorney for Applicants  
Heslin Rothenberg Farley & Mesiti P.C.  
Telephone: (518) 452-5600  
Facsimile: (518) 452-5579  
**Customer Number 23405**